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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/511,341 | 08/25/2005 | Katsutoshi Sasaki | BJS-4093-8 | 3748 |

23117 7590 03/17/2008
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| EXAMINER |
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VOGEL, NANCY S

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| ART UNIT | PAPER NUMBER |
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1636

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| MAIL DATE | DELIVERY MODE |
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03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/511,341 | Applicant(s) SASAKI ET AL. | |
| | Examiner NANCY VOGEL | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/15/04, 6/8/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 68-77 are pending in the case.

Receipt of the Information Disclosure Statement on 6/8/06 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 68-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braselmann et al. (Proc. Natl. Acad. Sci. USA 90:1657-1661, 1993) in view of Miyaji et al. (Cytotechnology, 4(2):173-180, 1990).

Braselmann et al. disclose a mammalian cell comprising a DNA construct for expression of a transcription factor necessary for construction of an inducible expression system, wherein the transcription factor is a chimeric protein of a ligand binding domain of estrogen receptor and yeast Gal4p. Braselmann et al. disclose cells comprising in addition DNA construction where a reporter gene is ligated at the downstream area of a promoter having a responsive element of a transcription factor, which is the a Gal4- responsive promoter linked to a reporter gene which is a c-fos gene or a CAT gene (see Fig. 1 and page 1658). The reference teaches that the disclosed expression control system may be used in other tissue culture cells (see page 1657, second column, second complete paragraph).

The difference between the reference and the instant claims is that the cell in which the constructs are present is the Namalwa KJM-1 cell which is adapted for serum-free culture.

However, Miyaji et al. disclose Namalwa KJM-1 cells adapted for serum-free culture, and disclose the usefulness of said cells for foreign gene expression (see page 173). It would have been obvious to one of ordinary skill in the art to have utilized the cells disclosed by Miyaji et al. as the host cell for the expression system disclosed by Braselmann et al., since Miyaji et al. and Braselmann each are concerned with the expression of foreign genes in tissue culture cells of interest. One would have been motivated to do so by the disclosure of Braselmann et al. of the usefulness of the disclosed expression system for control of expression of genes in any tissue culture cell of interest, and in view of the usefulness of the KJM-1 Namalwa cells for expression of foreign genes and production of proteins of interest. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 68-73 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braselmann et al. . (Proc. Natl. Acad. Sci. USA 90:1657-1661, 1993) in view of Miyaji et al. (Cytotechnology, 4(2):173-180, 1990), and further in view of Scheirer (US Patent 5,866,342).

Braselmann et al and Miyaji et al. are cited essentially for the reasons set forth above.

The difference between the references and the instant claims is that luciferase is used as the reporter gene.

However, Scheirer discloses lymphoblastoid cells comprising DNA constructs comprising a promoter linked to the luciferase reporter gene (see col. 8). It would have been obvious to one of ordinary skill in the art to have utilized a well known reporter gene such as luciferase gene disclosed by Scheirer in the constructs disclosed by Braselmann and Miyaji et al., since luciferase is known to be a useful reporter gene, and in the absence of unexpected results, the substitution of one reporter gene for another would have been obvious to one of ordinary skill in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 and by dependence claims 69-77 are vague and indefinite in the recitation of "DNA construct for expression of a transcription factor necessary for construction of an inducible expression system" and "CAN construct for expression of

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Galpha protein or a chimeric Galpha protein" since it is not clear whether the DNA encoding the transcription factor or G proteins are intended to be present, or whether it is intended that only such elements as a promoter are present, into which DNA encoding the transcription factor or G protein may be linked in order to produce a transcription factor or G protein.

Claims 68 and by dependence claims 69-77 are vague and indefinite in the recitation of the term 'derived from' a B-cell line. "Derived" is a term that is non-specific and relative in nature for which Applicant provides no definition. It provides no clarity as to what Applicant's claimed invention includes and what it does not include. Without a more specific definition, it is impossible to determine what and how many derivations comprise the invention. The nature and number of the derivations to arrive at the invention Applicant seeks to protect with the patent are not established such that a person skilled in the art would be apprised of the metes and bounds of the claims. The limits of the inventions cannot be discerned and others could not know if they were infringing Applicant's claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
3/2/08